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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,211	03/18/2004	Natarajan Ranganathan	KBI-0022	5830

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04/28/2005

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EXAMINER

DAVIS, RUTH A

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 04/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/803,211	Applicant(s) RANGANATHAN, NATARAJAN	
	Examiner Ruth A. Davis	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 6-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/04; 1/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1 – 5 and 13 in the reply filed on March 7, 2005 is acknowledged. The traversal is on the grounds that the inventions are not distinct, that the search for one group would inherently reveal references regarding the other groups, and that there is no burden on examiner. This is not found persuasive because as stated in the previous office action, the groups are distinct in that other materially different products could be used to treat accomplish the methods of groups I and III, such as taurine and burdock root; or colostrum. In addition, compositions comprising *Bacillus* or *Lactobacillus* could be used in other methods such as aiding digestion, or fermenting food products. Further, applicant is reminded that an overlapping search is NOT a co-extensive search. Thus, while the search for one group may overlap that of another, the searches are not co-extensive. Therefore a burden exists on examiner, as also exemplified by the separate classification.

The requirement is still deemed proper and is therefore made FINAL.

Claims 6 – 12 are withdrawn from consideration, as being drawn to non-elected subject matter. Claims 1 – 5 and 13 have been considered on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3, 5 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 13 are rendered vague and indefinite for reciting "B." and "S." before the species, because it is unclear what genus of bacteria is being claimed. Since the claims include limitations to separate genus, it is unclear which genus species is being claimed (i.e. is B. longum Bacillus longum or Bifidobacterium longum). In addition, since applicant has not first spelled out the "S." genus, it is unclear what genus applicant is claiming.

Claim 5 is rendered vague and indefinite for reciting "a selected bacteria" because neither the claim language nor specification adequately define what applicant intends "a selected bacteria" to encompass. Moreover, it is unclear if a composition comprising any bacteria would meet the limitation of the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for

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patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1 – 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Zimmer (US 5501857).

Applicant claims a composition for augmenting kidney function in a subject, the composition comprising at least one probiotic bacteria, wherein the bacteria reduces creatine and BUN levels in a subject. The composition further comprises a gelatin coating; the bacteria is selected from *Lactobacillus acidophilus*, *L. bulgaricus*, *L. casei*, *L. rhamnosus*, *L. fermentum*, *L. salivarioes*, *L. brevis*, *L. plantarum*, *L. ruteri*, *B. pasteurii*, *S. thermophilus*, *Bacillus sporogenes*, *Bifidobacterium adolescentis*, *B. infantis*, *B. longum*, *B. thermophilus* or *B. bifidum*; the composition further comprises a vitamin and mineral. Applicant additionally claims a composition for treating renal failure, comprising a selected bacteria which converts nitrogenous wastes into non-toxic compounds, in vivo.

Zimmer teaches a composition comprising bacteria, vitamins and minerals (abstract) that is encapsulated with gelatin (col.4 line 40-45). The bacteria are selected from *Lactobacillus acidophilus*, *L. casei* and/or *Bifidobacterium* (col.8 line 25-35).

Although the reference does not teach the composition is used for the claimed purpose, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Moreover, the claimed function must be

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inherent to the reference composition. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. Thus the claiming of a new use, functions or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. (MPEP 2112) Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112). In addition, although the reference does not teach the bacteria exhibit the claimed activity, the bacteria are the same. Thus the bacteria of the reference composition must also, inherently, exhibit the claimed functions.

Therefore, the reference anticipates the claimed subject matter.

6. Claims 1, 3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Paul (US 5531988).

Applicant claims a composition for augmenting kidney function in a subject, the composition comprising at least one probiotic bacteria, wherein the bacteria reduces creatine and BUN levels in a subject. The bacteria is selected from *Lactobacillus acidophilus*, *L. bulgaricus*, *L. casei*, *L. rhamnosus*, *L. fermentum*, *L. salivaroos*, *L. brevis*, *L. plantarun*, *L. ruteri*, *B. pasteurii*, *S. thermophilus*, *Bacillus sporogenes*, *Bifidobacterium adolescentis*, *B. infantis*, *B. longum*, *B. thermophilus* or *B. bifidum*. Applicant additionally claims a composition for treating renal failure, comprising a selected bacteria which converts nitrogenous wastes into non-toxic compounds, *in vivo*.

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Paul teaches a composition comprising lactobacillus and/or Bifidobacterium (abstract), wherein the bacteria may be *L. acidophilus*, *B. adolescentis*, *L. bulgaricus*, *L. casei*, *L. fermentum*, *L. brevis*, *L. plantarum*, *B. infantis*, *B. longum*, *B. thermophilum*, or *B. bifidum* (col.5 line 19-34).

Although the reference does not teach the composition is used for the claimed purpose, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Moreover, the claimed function must be inherent to the reference composition. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. Thus the claiming of a new use, functions or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. (MPEP 2112) Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112). In addition, although the reference does not teach the bacteria exhibit the claimed activity, the bacteria are the same. Thus the bacteria of the reference composition must also, inherently, exhibit the claimed functions.

Therefore, the reference anticipates the claimed subject matter.

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7. Claims 1 – 3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by for (US 5733568).

Applicant claims a composition for augmenting kidney function in a subject, the composition comprising at least one probiotic bacteria, wherein the bacteria reduces creatine and BUN levels in a subject. The composition further comprises a gelatin coating; and the bacteria is selected from *Lactobacillus acidophilus*, *L. bulgaricus*, *L. casei*, *L.rhamnosus*, *L. fermentum*, *L. salivaroos*, *L. brevis*, *L. plantarun*, *L. ruteri*, *B. pasteurii*, *S. thermophilus*, *Bacillus sporogenes*, *Bifidobacterium adolescentis*, *B. infantis*, *B. longum*, *B. thermophilus* or *B. bifidum*. Applicant additionally claims a composition for treating renal failure, comprising a selected bacteria which converts nitrogenous wastes into non-toxic compounds, in vivo.

Ford teaches compositions comprising lactobacillus bacteria (abstract) wherein the bacteria may be *L. acidophilus*, or *L. bulgaricus*, and the composition is coated with gelatin (col.6 line 25-30).

Although the reference does not teach the composition is used for the claimed purpose, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Moreover, the claimed function must be inherent to the reference composition. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. Thus the claiming of a new use, functions or

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unknown property which is inherently present in the prior art does not necessarily make the claim patentable. (MPEP 2112) Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112). In addition, although the reference does not teach the bacteria exhibit the claimed activity, the bacteria are the same. Thus the bacteria of the reference composition must also, inherently, exhibit the claimed functions.

Therefore, the reference anticipates the claimed subject matter.

8. Claims 1 and 3 – 5 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Langrehr (US 5785990).

Applicant claims a composition for augmenting kidney function in a subject, the composition comprising at least one probiotic bacteria, wherein the bacteria reduces creatine and BUN levels in a subject. The composition further comprises vitamins and minerals; and the bacteria is selected from *Lactobacillus acidophilus*, *L. bulgaricus*, *L. casei*, *L. rhamnosus*, *L. fermentum*, *L. salivarius*, *L. brevis*, *L. plantarum*, *L. ruteri*, *B. pasteurii*, *S. thermophilus*, *Bacillus sporogenes*, *Bifidobacterium adolescentis*, *B. infantis*, *B. longum*, *B. thermophilus* or *B. bifidum*. Applicant additionally claims a composition for treating renal failure, comprising a selected bacteria which converts nitrogenous wastes into non-toxic compounds, in vivo.

Langrehr teaches compositions comprising vitamins, minerals and bacteria selected from *Bifidobacterium bifidum*, *L. acidophilus*, and/or *L. casei*.

Although the reference does not teach the composition is used for the claimed purpose, the intended use of the claimed composition does not patentably distinguish the composition, per

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se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Moreover, the claimed function must be inherent to the reference composition. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. Thus the claiming of a new use, functions or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. (MPEP 2112) Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112). In addition, although the reference does not teach the bacteria exhibit the claimed activity, the bacteria are the same. Thus the bacteria of the reference composition must also, inherently, exhibit the claimed functions.

Therefore, the reference anticipates the claimed subject matter.

9. Claims 1 and 3 – 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Halpin-Dohnalek et al (US 5902578).

Applicant claims a composition for augmenting kidney function in a subject, the composition comprising at least one probiotic bacteria, wherein the bacteria reduces creatine and BUN levels in a subject. The composition further comprises vitamins and minerals; and the bacteria is selected from *Lactobacillus acidophilus*, *L. bulgaricus*, *L. casei*, *L. rhamnosus*, *L. fermentum*, *L. salivarioes*, *L. brevis*, *L. plantarum*, *L. ruteri*, *B. pasteurii*, *S. thermophilus*, *Bacillus*

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sporogenes, Bifidobacterium adolescentis, B. infantis, B. longum, B. thermophilus or B. bifidum.

Applicant additionally claims a composition for treating renal failure, comprising a selected bacteria which converts nitrogenous wastes into non-toxic compounds, in vivo.

Halpin-Dohnalek teaches compositions comprising minerals, vitamins, and bacteria selected from L. acidophilus, or L. reuteri, and/or B. infantis (col.3 line 40-45).

Although the reference does not teach the composition is used for the claimed purpose, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Moreover, the claimed function must be inherent to the reference composition. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. Thus the claiming of a new use, functions or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. (MPEP 2112) Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112). In addition, although the reference does not teach the bacteria exhibit the claimed activity, the bacteria are the same. Thus the bacteria of the reference composition must also, inherently, exhibit the claimed functions.

Therefore, the reference anticipates the claimed subject matter.

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10. Claims 1, 3 – 5 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Reddy et al. (US 6080401).

Applicant claims a composition for augmenting kidney function in a subject, the composition comprising at least one probiotic bacteria, wherein the bacteria reduces creatine and BUN levels in a subject. The composition further comprises vitamins and minerals; and the bacteria is selected from *Lactobacillus acidophilus*, *L. bulgaricus*, *L. casei*, *L. rhamnosus*, *L. fermentum*, *L. salivarius*, *L. brevis*, *L. plantarum*, *L. ruteri*, *B. pasteurii*, *S. thermophilus*, *Bacillus sporogenes*, *Bifidobacterium adolescentis*, *B. infantis*, *B. longum*, *B. thermophilus* or *B. bifidum*. Specifically the bacteria is *L. acidophilus*, *A. thermophilus* and *B. longum*. Applicant additionally claims a composition for treating renal failure, comprising a selected bacteria which converts nitrogenous wastes into non-toxic compounds, in vivo.

Reddy teaches compositions comprising probiotics selected from *L. bulgaricus*, *L. acidophilus*, *L. casei*, *S. thermophilus*, *B. bifidus* and/or *B. longum* (col.9 line 31-41) combined with vitamins and minerals (claims).

Although the reference does not teach the composition is used for the claimed purpose, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Moreover, the claimed function must be inherent to the reference composition. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not

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render the old composition patentably new. Thus the claiming of a new use, functions or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. (MPEP 2112) Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112). In addition, although the reference does not teach the bacteria exhibit the claimed activity, the bacteria are the same. Thus the bacteria of the reference composition must also, inherently, exhibit the claimed functions.

Therefore, the reference anticipates the claimed subject matter.

Double Patenting

11. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

12. Claim 5 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of copending Application No. 10/676,622. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1 – 5 and 13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 – 3 of copending Application No. 10/676,622. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are to compositions comprising the same bacteria, in combination with vitamins, minerals and coatings. At the time of the claimed invention, it would have been obvious to include vitamins, minerals and gelatin coatings with the instant bacteria, as it was common to do so at the time the claimed invention was made (in support, see cited references above).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 1 – 5 and 13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, 8 and 10 of copending Application No. 10/689,359. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are to compositions comprising the same

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bacteria, in combination with vitamins, minerals and coatings. At the time of the claimed invention, it would have been obvious to include vitamins, minerals and gelatin coatings with the instant bacteria, as it was common to do so at the time the claimed invention was made (in support, see cited references above).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis

A handwritten signature in black ink, appearing to read 'R. Davis', is written over the printed name.

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